

**LEGISLATIVE SERVICES AGENCY
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FISCAL IMPACT STATEMENT

LS 7359

BILL NUMBER: HB 1315

NOTE PREPARED: Apr 9, 2013

BILL AMENDED: Mar 18, 2013

SUBJECT: Biosimilar Biological Products.

FIRST AUTHOR: Rep. Clere

FIRST SPONSOR: Sen. Patricia Miller

BILL STATUS: 2nd Reading - 2nd House

FUNDS AFFECTED: X **GENERAL**
DEDICATED
FEDERAL

IMPACT: State

Summary of Legislation: (Amended) The bill requires the Health Finance Commission to study, during the 2013 legislative interim, how Indiana law should address the prescribing and substituting of biosimilar biological products.

Effective Date: July 1, 2013.

Explanation of State Expenditures: (Revised) *Health Finance Commission:* The study would have to be conducted during the 2013 interim. If the Commission were to hold additional meetings to address this topic, there would be additional expenditures for legislator per diem and travel reimbursement for the commission members. Any additional expenditures must be within the commission's budget, which is established by the Legislative Council.

Background Information - Biosimilar Biological Products: Current Indiana law provides for the substitution of generic drugs for brand name drugs but does not provide for the substitution of the new biotech drugs defined as biological products. The bill defines biological products, biosimilar products, and interchangeable biosimilar products. The bill allows for the substitution of interchangeable biosimilar products for the biological products by a pharmacist so long as the prescriber is notified of the substitution within five days. Biological products (brand names) are currently sold in the U.S. A few copies or biosimilar products are sold in Europe but these are not yet available within the U.S. The Food and Drug Administration is currently working on rules for introducing biosimilars - defining a process different from that for generic drugs to demonstrate the safety, efficacy, and interchangeability of biosimilar products. Currently, there are no

biosimilar interchangeable drugs available on the U.S. market.

Explanation of State Revenues:

Explanation of Local Expenditures:

Explanation of Local Revenues:

State Agencies Affected: IPLA, Board of Pharmacy; LSA.

Local Agencies Affected:

Information Sources: IPLA.

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